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A Phase IIa study of NTRX-07 in Alzheimer's patients

Isa drug targeting inflammation safe and tolerable in people living with Alzheimer's?

Background
In addition to the accumulation of beta-amyloid plaques and tau tangles, inflammation in the brain is becoming increasingly recognized as a key factor in Alzheimer's disease. During Alzheimer's, immune cells in the brain known as microglia can become activated and release substances that promote brain inflammation and may lead to nerve cell damage. Novel treatments that target brain inflammation could potentially help to slow or prevent Alzheimer's disease.

NTRX-07 is an experimental drug that has been shown to reduce brain inflammation and improve cognitive function in genetically engineered Alzheimer's-like mice. NTRX-07 binds to a receptor or "docking site" on the surface of microglia known as the cannabinoid type 2 (CB2) receptor. NTRX-07 is believed to reduce the activation of microglia, and thereby reduce inflammation in the brain.

Dr. Joseph Foss and colleagues previously conducted a Phase 1 clinical study of NTRX-07 in healthy volunteer participants to study its safety and pharmacokinetics (how the drug is absorbed and eliminated by the body). Now that the researchers have determined a safe and optimal dosing regimen, they will conduct a further clinical trial of NTRX-07 in individuals with Alzheimer's.

Research Plan
For this Phase 2a clinical trial, Dr. Foss and colleagues will study the impact of NTRX-07 treatment on individuals with Alzheimer's. After 28 days of treatment with either a high dose, low dose, or placebo, the researchers will assess the safety and tolerability of the drug, as well as measure potential changes in cognitive tests, brain scans (electroencephalography, EEG), and brain activity (P600 event-related potential, ERP). The team will also use a brain imaging method called free-water magnetic resonance imaging (MRI) to assess changes in brain inflammation. Finally, they will measure changes in biological markers (biomarkers) associated with inflammation, microglial activity, and Alzheimer's in samples of blood and cerebrospinal fluid (CSF, a biological fluid surrounding the brain and spinal cord). Additionally, Dr. Foss

and colleagues will determine whether changes in CSF biomarkers predict changes in blood biomarkers.

Impact

If successful, this study may support the development of NTRX-07 as a potential therapy to reduce brain inflammation and help slow or halt the progression of Alzheimer's disease.